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| 09/751,023 | 12/29/2000 | G. Ian Rowlandson | 31-CD-5530 | 7713 |

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| EXAMINER | |
|---|---|
| GOTTSCHALK, MARTIN A | |
| ART UNIT | PAPER NUMBER |
| 3694 | |

DATE MAILED: 10/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/751,023 | ROWLANDSON, G. IAN | |
| | Examiner | Art Unit | |
| | Martin A. Gottschalk | 3626 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *28 April 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-11 and 16-27* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11 and 16-27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

### *Notice to Applicant*

1. This Office Action is a new Final Action issued following the Pre-Appeal Conference decision mailed 07/18/2006. Claims 1-11 and 16-27 have been examined. Claims 1 and 16 have been amended. Claims 12-15 have been cancelled.

### *Claim Rejections - 35 USC § 103*

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. Claims 1, 4, 5, 7, 11, 16, 19-21, and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fujimoto (US Pat# 5,339,821, hereinafter Fujimoto) in view of

Coolidge et al (US Pat# 2002/0107206, hereinafter Coolidge), and further in view of Bayne (PG Pub# US 2005/0060198, hereinafter Bayne).

A. As per claim1, Fujimoto discloses a method for scheduling an emergency procedure, comprising the steps of:

acquiring an electrocardiogram record for a particular patient (Fujimoto: col 5, lns 14-52);

sending said electrocardiogram record to a computer (Fujimoto: col 8, lns 8-13);

said computer determining that said particular patient has a high probability of acute coronary disease based at least partly on an automated analysis of data in said electrocardiogram record (Fujimoto: col 8, lns 25-31);

Fujimoto fails to explicitly teach the diagnosis of **acute coronary syndrome** (ACS), however, this feature is well known in the art as evidenced by the teachings of Coolidge who teaches the diagnosis of ACS employing electrocardiogram (ECG) data (Coolidge: [0002]), as well as the stratification of this diagnosis into subtypes (Coolidge: [0020], [0025]-[0026]).

It would have been obvious to one of ordinary skill in the art at the time of the invention to incorporate the teachings of Coolidge and Fujimoto with the motivation of improving the treatment of ACS through early diagnosis and therapy with agents that prevent or reduce damage due to ACS (Coolidge: [0009]).

Fujimoto and Coolidge fail to disclose the remaining steps of claim 1, however, these features are well known in the art as evidenced by the teachings of Bayne who teaches

> said computer automatically routing a communication (Bayne: Fig. 1, item 114 - the "triage processing block"; [0032], lns 1-10; [0078], in particular lns 9-11, wherein the claim reads on "...an emergency request automatically generated in response to a condition...") to an electronic device accessible to a cardiologist on call (Bayne: [0073], lns 11-12), in response to said determination that said particular patient has a high probability of acute coronary syndrome, said communication comprising said electrocardiogram record and results of said automated analysis (See Bayne: [0078] who teaches a remote internet capable medical device determining that an emergency condition exists, and subsequently transmitting an automated request for assistance to a computer system designed to provide such assistance. Bayne: [0037] also suggests the use of ECG machines on-site at the patient's location which could provide such information. Bayne: Fig 5 and [0082] further discloses the use of expert system

software which makes a medical diagnosis by analyzing the data generated by the remote device. The Examiner considers an expert system operating on electrocardiogram data to be a form of automated analysis that determines whether or not a patient has a high probability of acute coronary syndrome. Further note Bayne: [0083], where in response determining the existence a particular medical condition decides what type of clinician would be most appropriate and routes a communication to an on-call clinician by way of the "clinician device", [0086], and see Bayne: [0073], and Fig 4 noting in particular the example of a cardiologist as clinician.);

in response to a predetermined message from the cardiologist indicating that said patient should undergo an emergency procedure for treatment of acute coronary syndrome, said computer automatically scheduling said emergency procedure at an emergency coronary treatment facility (Bayne: [0098]. Note the clinician providing a pre-determined message concerning scheduling an appointment. Also note in the same passage the distinction made between "manually" scheduling appointments and using the system to do so, i.e. doing it automatically. It is further noted that the conditional statement "...if the patient's condition warrants..." includes needing an emergency procedure. Note further in the same passage the disclosure of the clinician's message notifying the remotely located call center computer's "pre-scheduled appointment information block with follow-up information", such as to make an appointment. See further

Bayne: [0080], lns 10-14 which discloses the ability of the call center's computer to automatically make an appointment with an emergency coronary treatment facility. The exemplary facility provided in the passage is an ambulance, but might include other types of facilities.).

It would have been obvious to one of ordinary skill in the art to incorporate the teachings of Bayne with the combined teachings of Fujimoto and Coolidge with the motivation of properly discriminating between medical situations requiring emergency services such as an ambulance and situations where the patient might be more appropriately be served in the home (Bayne: [0007]-[0009]).

B. As per claims 4, 5, 7, and 11, besides the amendments provided by claim 1 from which they depend, they are otherwise unamended, and as such, are rejected for the same reasons provided in the first Office Action.

C. As per claims 16, it is a system claim which repeats the same limitations of claim 1, the corresponding method claim, as a collection of elements as opposed to a series of process steps. Since the teachings of Fujimoto, Coolidge, and Bayne disclose the underlying process steps that constitute the method of claim 1, it is respectfully submitted that they provide the underlying structural elements that perform the steps as well. As such, the limitations of claims 16 is rejected for the same reasons given above for claim 1.

D. As per claims 19-21, 23, and 24, besides the amendments provided by claim 16 from which they depend, they are otherwise unamended, and as such, are rejected for the same reasons provided in the first Office Action.

5. Claims 2, 3, 6, 8-10, 17, 18, 22, and 25-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fujimoto, in view of Coolidge and Bayne as applied to claim 1 above, and further in view of the admitted prior art in the current application (PG Pub# 2002/0087355; hereinafter "the admitted prior art" or APA).

Note: In the following paragraphs, although claims 2, 3 and 6 are unamended, they are presented here as they were in the first Office Action for convenience.

A. As per claims 2 and 3 over Fujimoto, Coolidge and Bayne fail to disclose a method wherein

(Claim 2) said emergency coronary treatment facility is a catheterization lab; and

(Claim 3) said emergency procedure is percutaneous transluminal coronary angioplasty.

However, this feature is well known in the art as evidenced by the teachings of the admitted prior art.

In particular, the admitted prior art discloses that a catheterization lab is an emergency coronary treatment facility for performing procedures such as the percutaneous transluminal coronary angioplasty, or PTCA (APA: [0017]).

It would have been obvious to one skilled in the art at the time of the invention to modify the automated scheduling features taught by Bayne by incorporating the teachings of the admitted prior art. The motivation of this combination would have been to improve the ability of patients to quickly obtain medical care for acute conditions (Bayne: [0008]).

B. As per claim 6, Bayne discloses a method wherein said automatic scheduling step comprises the steps of

> accessing a respective schedule for each of a plurality of emergency coronary treatment facilities (Bayne: Fig. 1, item 116 - "pre-scheduled appointment block"; [0034]. The Examiner considers that this block could be programmed to access the schedules of the treatment facilities. See also Fig. 1, item 136 – "local hospital admissions"; [0040]. Note that communication with local hospital admissions resources would provide access to schedules for the treatment facilities within the hospitals.), and

selecting an emergency coronary treatment facility (Bayne: [0050]. Note that "...coordinating levels of service," is stated as a purpose of the local hospital admissions link. The Examiner considers an emergency coronary treatment to be an example of a level of service in need of coordination.)

Fujimoto, Coolidge and Bayne fail to disclose

an emergency coronary treatment facility having an optimum time-to-treatment.

However, this feature is well known as evidenced by the teachings of the admitted prior art.

The admitted prior art teaches the importance of minimizing time-to-treatment in lowering the mortality rate of the PTCA procedure (APA: [0017], lns 8-23).

The motivation to combine the teachings of Bayne and the admitted prior art is the same as provided above for claim 6 and are incorporated herein.

C. As per claims 8-10, besides the amendments provided by claim 1 from which they depend, they are otherwise unamended, and as such, are rejected for the same reasons provided in the first Office Action.

D. As per claims 17, 18, 22, and 25-27, besides the amendments provided by claim 16 from which they depend, they are otherwise unamended, and as such, are rejected for the same reasons provided in the first Office Action.

***Response to Arguments***

6. Applicant's arguments in the response filed 12/05/2005 and 04/28/2006 have been fully considered. Applicant's arguments in the latter response are largely the same as provided in the former, and were found non-pursuasive as described below. In the latter response however, Applicant points out the occurrence in claim 1 wherein the passages provided for "said computer" refer to different computers in one instance (for example pg 2 of the latter response), and as such, the applied reference (Bayne) is inappropriate as an anticipatory reference under 35 U.S.C, section 102. This argument is found persuasive, and in response, new grounds of rejection have been introduced for claim 1 above.

The remaining arguments in are found non-pursuasive and will be addressed below in the order in which they appear in the REMARKS section of the response filed 12/05/2005. Paragraph F responds to an argument provided in the response of 04/28/2005 which as found non-pursuasive.

A. On pages 8 and 9 of the response, regarding amended claims 1 and 16, Applicant argues that the Bayne reference does not teach certain features of Applicant's invention.

For example, on page 8, third paragraph, applicant states that, "Bayne does not teach scheduling a particular emergency medical procedure at a particular treatment facility at a particular time." In response, the Examiner respectfully points out that Applicant does not claim scheduling at a particular time, but rather in claim 1 (and 16) recites "scheduling said (an) emergency procedure at an (said) emergency coronary treatment facility." The only possible indication of scheduling a particular time would be in the word "emergency", which the Examiner considers to mean as soon as possible. With respect to scheduling a particular emergency medical procedure at a particular facility (i.e. an emergency coronary treatment facility), the Examiner respectfully disagrees with the assertion that the reference does not teach these features, and refers Applicant to the reasons provided for the rejection of claim 1, the third and last steps in particular.

Applicant further asserts in paragraph 4 starting on page 8, that the reference does not disclose that a patient may transmit an electrocardiogram during a phone call into the call center. In response, the Examiner again wishes to point out that Applicant does not claim this feature, thus the relevance of this argument is not apparent.

In this same paragraph, on page 9, appears to argue that Bayne does not disclose diagnosis of an acute cardiac condition with a subsequent response (such as scheduling a procedure). This argument is moot in view of the new grounds of rejection provided above for claim 1.

In the second paragraph on page 9, applicant appears to argue that Bayne does not disclose a computer programmed to perform certain recited steps. In response, the Examiner respectfully disagrees, and refers Applicant to the reasons provided for rejection of claim 1, noting in particular the references to the disclosure by Bayne of the use of an expert system for diagnosis, the communications between the call center computer, the clinician, the triage module, and the pre-scheduled appointment information block.

B. On page 10, regarding claims 2 and 3, Applicant appears to argue that a prima facie case of obviousness to combine the teachings of the admitted prior art with the references provided for claim 1 has not been made.

In response to Applicant's argument that there is no suggestion to combine the references, the Examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in

the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992).

In this case, Applicant asserts that it would not be obvious to modify the references provided for claim 1, in particular the automated scheduling features taught by Bayne by incorporating into it the scheduling of a PTCA procedure at an emergency coronary treatment facility. The Examiner refers Applicant to the reasons and motivation to combine references provided for the rejection of claims 2 and 3 in the first Office Action. In particular, note, as per the reasons provided for the rejection of claim 1 above and from which these claims depend, that Bayne teaches scheduling an emergency coronary procedure. Applicant will further recognize from the admitted prior art that PTCA is well known in the art as an important type of such a procedure. Therefore it is reasonable (and thus obvious to one of ordinary skill in the art) to modify the teachings of Bayne to include scheduling PTCA, which clearly could only be performed at a facility with the capability to perform the procedure.

C. In the last paragraph on page 6, regarding the reasons provided for the rejection of claim 6 in the first Office Action, Applicant appears to object to the use of the word "could" in the phrase "...could be programmed...", and asserts that the "mere possibility of doing something does not establish a prima-facie case for obviousness." The Examiner respectfully disagrees and wishes to clarify that the word "could" is not meant to convey uncertainty, nor unlimited, non-specific possibility, but rather is indicative of a

logical inference flowing from the suggestion provided by the reference of a "pre-scheduled appointment block." In other words, one of ordinary skill in the art concerning emergency coronary care might logically pose the hypothetical question, "For what is this block <i.e. computer and program> making an appointment?" Given the context of an emergency medical situation and the disclosed system designed to deal with such a situation, it would be logical for such an artisan to modify the system by programming it to schedule an appointment for a necessary emergency procedure at a facility capable of performing the procedure. Note further the suggestion that in order to implement such a program, access to relevant facility information would need to be obtained.

D. Also in this paragraph, in the reasons provided for claim 6 in the first Office Action, Applicant disagrees with the Examiner's observation that "communication with local hospital admissions resources would provide access to schedules for the treatment facilities within the hospitals." In response, the Examiner maintains the apparent validity of this statement, and further notes that perhaps the best source of information for finding out the availability of a hospital's treatment facilities would be none other than the information available from the admissions department of the hospital itself. Note further the disclosure provided by Bayne: Fig 1, [0044] and [0050] of the communication connection between the call center, clinician device, and local hospital admissions.

E. Also in this paragraph, Applicant states that " the 'treatment facilities' recited in claim 6 would obviously not be accessible from the admissions office of a single hospital." In response, the Examiner respectfully disagrees and recalls the reference to Bayne provided in paragraph D above, and notes that there is nothing in the teaching of Bayne that limits access to communication with a single hospital, and logically, such a system would be in communication with a plurality of hospitals to cover the possibility of admissions to any and each of them.

F. On page 7 of response filed 04/28/2006, Applicant appears to argue that the system taught by Bayne will not respond to an emergency situation (e.g. pg 3), and indeed, "teaches away" (pg 7) from such a feature. In response, Applicant is referred, for example, to Bayne: [0080] which discloses a medical device (such as an ECG, located on-site where the patient is located) notifying the central computer of the existence of a "life threatening emergency" condition, wherein said computer responds by calling an ambulance on behalf of the patient, i.e. the computer performs an automated scheduling of emergency facilities.

***Conclusion***

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Martin A. Gottschalk whose telephone number is (571) 272-7030. The examiner can normally be reached on Mon - Thurs 8:30 -6 and alternate Fri 8:30 - 5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Thomas can be reached on (571) 272-6776. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MG
08/18/2006

JOSEPH THOMAS
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